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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/738,938

12/17/2003

Raul G. Barletta

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EXAMINER

RAMIREZ, DELIA M

ART UNIT

PAPER NUMBER

1652

MAIL DATE

DELIVERY MODE

07/27/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/738,938

Applicant(s)

BARLETTA ET AL.

Examiner

Delia M. Ramirez

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 6, 11, 12 and 24-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6, 11, 26 and 27 is/are allowed.
- 6) ☒ Claim(s) 12, 24, 25 and 28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 4/23/2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of the Application***

Claims 6, 11-12, 24-28 are pending.

Applicant's amendment of claims 6, 11-12, cancellation of claims 1-5, 7-10, 13, addition of claims 24-28, amendments to the specification and the drawings as submitted in a communication filed on 4/23/2007 are acknowledged.

New claim 24 is directed to the microorganism of claim 11, new claim 26 is directed to a plasmid comprising the DNA fragment encoding the *M. tuberculosis* Ddl gene, and new claims 26-28 are directed to a method for producing a recombinant microorganism with the plasmid of claim 6. While the subject matter of new claims 26-28 was not previously examined as was not present in the claims as originally filed, in the interest of advancing prosecution, the examiner will examine these claims. Claims 6, 11-12, 24-28 are at issue and are being examined herein.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

### ***Drawings***

1. In view of applicant's submission of corrected Figure 6, the previous objection to the drawings is hereby withdrawn.

### ***Claim Objections***

2. Claim 25 is objected to due to the recitation of "first six codons of *M. bovis* BCG hsp60, and operably linked to said *M. bovis* BCG hsp60 promoter,...". As written, it appears as if the DNA fragment should be fused to the *M. bovis* BCG hsp60 protein. Also, there is no antecedent basis for the promoter. For clarity and taking into consideration the teachings of the specification (paragraph [80]), the term

Art Unit: 1652

should be amended to recite "first six codons of the *M. bovis* BCG hsp60 gene, and operably linked to the promoter of the *M. bovis* BCG hsp60 gene,...". Appropriate correction is required.

***Claim Rejections - 35 USC § 112, Second Paragraph***

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claim 12 remains rejected and new claim 28 is under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These new grounds of rejection are necessitated by applicant's amendment.
5. Claim 12 is indefinite in the recitation of "group consisting of ..., and any subspecies of said mycobacterium strains or genetic mycobacterium variants thereof" for the following reasons. As written, it is unclear as to how the term "genetic mycobacterium variants thereof" further limits the claim. The claim requires any subspecies of the mycobacterium strains previously recited. This encompasses any naturally found as well as any genetically modified strain/subspecies of *M. smegmatis*, *M. tuberculosis*, *M. bovis*, *M. africanum*, *M. microti*, *M. leprae*, *M. avium*, *M. intracellular*, *M. paratuberculosis*, *M. ulcerans*, or *M. marinum*. Genetic mycobacterium variants of subspecies of *M. smegmatis*, *M. tuberculosis*, *M. bovis*, *M. africanum*, *M. microti*, *M. leprae*, *M. avium*, *M. intracellular*, *M. paratuberculosis*, *M. ulcerans*, or *M. marinum* are already encompassed by the claim unless the genetic variation is such that they can no longer be classified in the recited species (i.e., no longer *M. smegmatis*, *M. tuberculosis*, *M. bovis*, *M. africanum*, *M. microti*, *M. leprae*, *M. avium*, *M. intracellular*, *M. paratuberculosis*, *M. ulcerans*, or *M. marinum*". Therefore, as written, it is unclear if the term "genetic mycobacterium variants thereof" is redundant or if it is intended to encompass any mycobacterium beyond those species recited. Correction/clarification is required.

Art Unit: 1652

6. Claim 28 is indefinite in the recitation of "producing a microorganism with an altered level of D-alanine ligase expression relative to a non-transformed microorganism" for the following reasons. As written, the level of D-alanine ligase expression is compared relative to any non-transformed organism and not necessarily with the corresponding non-transformed microorganism. For example, as written the claims allows comparison of the level of D-alanine ligase expression of an *E. coli* strain transformed with the plasmid of claim 6 and the level of D-alanine ligase expression of a wild-type *S. cerevisiae* strain. For examination purposes, it will be assumed that the term reads "producing a microorganism with an altered level of D-alanine ligase expression relative to the corresponding non-transformed microorganism".

Correction is required.

***Claim Rejections - 35 USC § 112, First Paragraph***

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 24 and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is a new rejection necessitated by amendment.

9. Claim 24 is directed to a recombinant mycobacterium strain GPM265. Claim 25 is directed to a plasmid which requires the *E. coli* shuttle vector pMV262. The invention appears to employ novel vectors/microorganisms. Since the vectors/microorganisms are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The vector's sequences have not been disclosed or shown to be publicly known. Similarly, there is no indication in the specification that the recombinant strain is publicly available. Accordingly, it

Art Unit: 1652

is deemed that a deposit of these vectors/microorganisms should have been made in accordance with 37 CFR 1.801-1.809.

It is noted that neither the specification nor the response filed on 4/23/2007 indicate whether the biological deposit ATCC PTA-8190 (contains pBUN276) contains strain GPM265. Also, while the specification discloses that plasmid pBUN276 was made using sections of plasmid pMV262, the plasmid of claim 25 does not have to be plasmid pBUN276 as it may contain other elements not found in pBUN276 but found in pMV262. Plasmid pMV262 is essential to make the plasmid of claim 25. If a deposit of strain GPM265 and plasmid pMV262 has been made under the terms of the Budapest treaty, then an affidavit or declaration by applicant, or a statement by an attorney of record over his/her signature and registration number, stating that the specific vector/microorganism have been deposited under the Budapest treaty and that the vector/microorganism will be available to the public under the conditions specified in 37 CFR 1.808 would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance or compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

- a. during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- b. upon granting of the patent the vectors/microorganisms will be available to the public under the conditions specified in 37 CFR 1.808;
- c. the deposit will be maintained in a public repository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and
- d. the deposit will be replaced if it should ever become unviable.

*Allowable Subject Matter*

10. Claims 6, 11, 26-27 appear to be allowable over the prior art of record.

*Conclusion*

11. Applicant's amendment of claim 12 and addition of claims 24-25, 28 necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571)

Application/Control Number: 10/738,938

Page 7

Art Unit: 1652

272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

A handwritten signature in black ink, appearing to read 'DMR', is positioned above the printed name.

Delia M. Ramirez, Ph.D.  
Primary Patent Examiner  
Art Unit 1652

DR  
July 22, 2007